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Display Date 2-27-02 @ 11:19a  
Publication Date 3-01-02  
Certifier R. LEDESMA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory  
Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 7, 2002, from 10:30 a.m. to 3:30 p.m., and on March 8, 2002, from 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Freddie-M. Poole, Center for Devices and \*Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-2096, ext. 111, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 7, 2002, the committee will discuss and make recommendations on the classification of preamendments in

vitro diagnostic products to identify Bacillus anthracis and Yersinia pestis. No applications will be reviewed at this meeting. On March 8, 2002, the committee will discuss, make recommendations, and vote on a supplement to a premarket approval application for a nucleic acid hybridization in vitro diagnostic device for the detection of 13 high-risk types of human papilloma virus DNA in cervical specimens. The test is indicated for use as a general population screening test in conjunction with the Papanicolaou smear for women 30 years of age and older, as an aid to determine the absence of high-grade cervical disease or cancer. The test is not intended for use as a screening test in the general population for women under 30 years of age.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the March 7 session will be posted on March 6, 2002; material for the March 8 session will be posted on March 7, 2002.

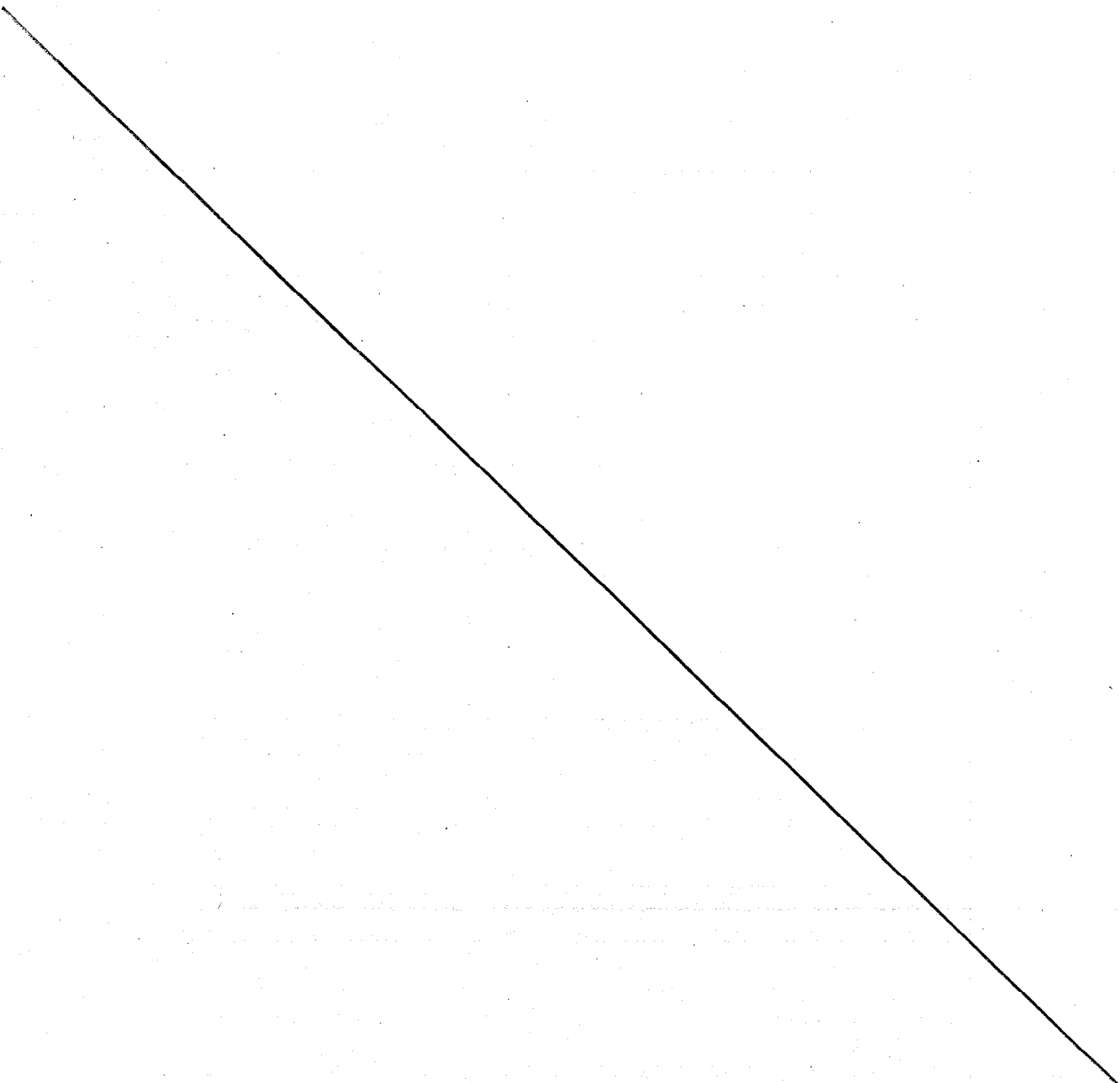
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 4, 2002. On March 7, 2002, formal oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:15 p.m., and between

approximately 2:30 p.m. and 2:45 p.m. On March 8, 2002, formal oral presentations from the public will be scheduled between approximately 11 a.m. and 11:45 a.m., and between approximately 3 p.m. and 3:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 4, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the March 8, 2002, Microbiology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Microbiology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing -access to electrical outlets.

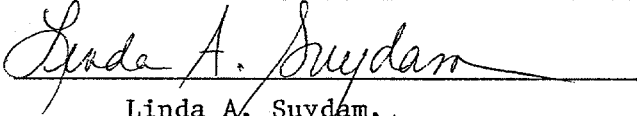
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, 301-594-1283, ext. 105, at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory  
Committee Act (5 U.S.C. app. 2).

Dated: 2-26-02

February 26, 2002.



Linda A. Suydam,  
Senior Associate Commissioner for  
Communications and Constituent Relations.

[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

Billing Code 4160-01-P

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